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08/967,243	11/05/97	LASKY	ATTY. DOCKET NO.
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08/967,243 11/05/97 LASKY

EXAMINER
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GENENTECH, INC.  
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SOUTH  
SAN FRANCISCO CA 94080-4990

HM12/0119

ART UNIT	PAPER NUMBER
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1649 35

DATE MAILED:

01/19/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

#### OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 1/2/01
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1, 15-25, 28 is/are pending in the application.  
Of the above, claim(s) 15-25 is/are withdrawn from consideration.
- ☐ Claim(s) is/are allowed.
- ☒ Claim(s) 1, 28 is/are rejected.
- ☐ Claim(s) is/are objected to.
- ☐ Claim(s) are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number)
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

### DETAILED ACTION

1. The request filed 1/2/01 (Paper No. 34) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/967,243 is acceptable and a CPA has been established. An Office Action on the CPA follows.

2. A restriction was required under 35 USC § 121 in the priority application, Paper No. 4 between the following Groups, as they read on pending claims.

- I. Claims 1 and 28, drawn to methods of inhibiting L-selectin binding with CD34.
- II. Claims 15-~~18~~, drawn to method of targeting active compounds with CD34-specific antibodies.
- III. Claim 19, drawn to methods of presenting carbohydrate antagonists of L-selectin-CD34 interactions.
- IV. Claim 20-25, drawn to bispecific molecules.

Applicant elected Group I with traverse in Paper No. 6.

This restriction requirement is hereby reiterated.

Accordingly, claims 15-25 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to the nonelected inventions.

Claims 2-14 and 26-27 have been canceled previously.

Claims 1 and 28 are under consideration and being acted upon.

3. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action. The rejections of record can be found in previous Office Actions (Paper Nos. 7/13/16/23/26/31). Given the absence of additional rebuttal to the outstanding rejections of record in applicant's amendment, filed 1/2/01 (Paper No. 34); the rejections are maintained for the reasons of record.

4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821-1.825 (see the specification at page 10, line 22). However, this application fails to comply with the requirements set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence.

The following procedure is to be used for cases that contain the same sequence disclosure as the parent. The applicant need not submit a new computer readable form of the Sequence Listing in this rule 60 continuation. However, (1) the specification must contain a paper copy of the Sequence Listing, (2) applicant must request in writing that the CRF in the parent case be used to prepare a file for the offspring and (3) applicant must submit a statement that the paper copy of the Sequence Listing in the offspring is identical to the computer readable form submitted in the parent case.

Applicant is required to fulfill these requirements

5. Again, applicant should update the status of the parent applications on the first line of the specification. USSN 08/256, 418 is now abandoned. Also, applicant is invited to clarify whether PCT/US9403791 is a continuation or a continuation-in-part of USSN 08/056,054. Compare the first line of the specification and the Oath/Declaration.

6. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 7.

As pointed out previously, it was noted that applicant has amended the Brief Description of the Drawings to include Figure 2 and that there was no Figure 2.

Upon a review, it appears that figures as filed were misnumbered and that the labeling a figure as Figure 2 was missing when the application was filed. This appears to have led to applicant's amendment of the Brief Description of the Drawings. It is presumed that applicant will make the appropriate corrections to the figures themselves, when formal figures will be submitted. Applicant is invited to clarify this issue.

Applicant will submit formal drawings upon the indication of allowable subject matter.

7. Claims 1 and 28 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "inhibiting the binding of native L-selectin to peripheral lymphoid tissue" and "contacting said L-selectin" for the reasons of record.

8. Claims 1 and 28 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record.

In vitro and animal model studies have not correlated well with in vivo clinical trial results in patients. Since the therapeutic indices of immunosuppressive drugs such as adhesion-based molecules can be species- and model-dependent, it is not clear that reliance on the identification of CD34 as L-selectin ligand and the expression of CD34 in various tissues and in certain inflammatory tissues accurately reflects the relative efficacy of the claimed methods for inhibiting the binding of L-selectin to peripheral lymphoid tissues in effective amounts sufficient to prevent or suppress the physiological conditions or symptoms which block the adhesive interactions between leukocytes (including lymphocytes, neutrophils and monocytes) and endothelial cells to treat pathological responses associated with leukocyte homing, including those encompassed by the number of inflammatory conditions disclosed in the specification as filed (see Therapeutic Applications on pages 17-20 of the specification).

9. Claim 28 stands objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The recitation of "CD34 isolated from peripheral lymph nodes" recited in claim 28 is essentially the same as that recited in claim 1 and does not further limit claim 1.

10. Claims 1 and 28 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Butcher et al. (U.S. Patent No. 5,538,724; see entire document) essentially for the reasons of record set forth in the previous Office Actions (Paper No. 7/13/16/23/26/31).

Applicant's arguments and the examiner's rebuttal are of record.

Applicant's arguments have been fully considered but have not been found convincing for the reasons of record.

11. Claims 1 and 28 stand rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Lasky et al. (U.S. Patent No. 5,304,640) essentially for the reasons of record set forth in the previous Office Actions (Paper Nos. 7/13/16/23/26/31).

Applicant's arguments and the examiner's rebuttal are of record.

Applicant's arguments have been fully considered but have not been found convincing for the reasons of record.

Applicant's arguments relying upon the Lasky/Rosen/Singer declaration under 37 C.F.R. § 1.132 alone are not found persuasive.

12. Claims 1 and 28 stand rejected under 35 U.S.C. § 103 as being unpatentable over Butcher et al. (U.S. Patent No. 5,538,724) or Lasky et al. (U.S. Patent No. 5,304,640) in view of Lasky et al. (CSHSQB, 1992; 1449, #35), Berg et al. (J. Cell Biol., 1991; 1449, #8) or Imai et al. (J. Cell Biol. 1991; 1449, #28), Sutherland et al. (Leukemia, 1988; 1449, #51), Lasky et al. (U.S. Patent No. 5,098,833; 1449, #2), Watson et al. (Nature, 1991; 1449, #55), Fina et al. (Blood, 1990; 1449, #22) and Schlingemann et al. (Lab. Invest., 1990; 1449, #42) essentially for the reasons of record set forth in the previous Office Actions (Paper Nos. 7/13/16/23/26/31).

Applicant's arguments and the examiner's rebuttal are of record.

Applicant's arguments have been fully considered but have not been found convincing for the reasons of record.

13. No claim is allowed.

14. All claims are drawn to the same invention claimed in the parent application prior to the filing of this Continued Prosecution Application under 37 CFR 1.53(d) and could have been finally rejected on the grounds and art of record in the next Office action. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing under 37 CFR 1.53(d). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

*Phillip Gambel*

Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
January 18, 2000